DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 17, 2014

Keeler Instruments Inc.
% Mr. Eugene R. Van Arsdale
Marketing Manager
459 Parkway
Broomall, PA 19008

Re: K142179
Trade/Device Name: Z-type Digital Keeler Applanation Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: August 7, 2014
Received: August 8, 2014

Dear Mr. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142179

Device Name
Z-type Digital Keeler Applanation Tonometer

Indications for Use *(Describe)*

The Z-type Digital Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Keeler
Ophthalmic Instruments

10. 510 (K) Summary of safety and Effectiveness

1. Submitter Name and Address

Keeler Instruments Inc.
459 Parkway
Broomall
PA 19008

Contact: Eugene R Van Arsdale (Marketing Manager)
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Date Prepared: June 2014

2. Device Name (Unmodified)

Trade Name:	Digital Keeler Applanation Tonometer (D-KAT)
Common/Usual Name:	T-Type D-KAT, R-Type D-KAT
Classification Name:	Tonometer and Accessories
Regulation No:	886.1930
Device Regulatory Class:	II
Review Panel:	Ophthalmic
Product Code:	HKY
Premarket Notification (510(k)) Number:	K093445

3. Proposed Modification

The proposed modification described in this Special 510(k) covers the dimensional changes to the current Digital Keeler Applanation Tonometer (D-KAT) to allow mounting of the device on the bottom-illuminating slit lamp (Zeiss-type illumination system).

In applanation tonometry the intraocular pressure (IOP) is calculated from the force required to flatten a constant area of the cornea. Goldmann tonometry is considered to be the gold standard test and is the most widely accepted method in current practice.

The new variant of the D-KAT uses the same operating principle found in all Goldmann type tonometers.

The internal mechanism of the new version of D-KAT (Z-type D-KAT) functions in the same way as the previously cleared model (T-type D-KAT, R-type D-KAT) and permits the measured IOP to be read on an LED display. The LED display allows for easy reading by the user. The dimensional modifications introduced in the current model allow the model to be fitted on Zeiss-type slit lamp.

The intended use of the Z-type Digital Keeler Applanation Tonometer (Z-type D-KAT) as well as the method used by the clinician to obtain a reading remains unchanged by this modification.

4. Device Description

The Z-type Digital Keeler Applanation Tonometer is a screening device used to measure intraocular pressure which is one of the factors considered in diagnosing glaucoma. The product is an active medical device, powered by a single AA battery. The operation principal is based on Goldmann applanation method.

The Indications for Use, Operating principles, measurement accuracy and repeatability are the same as the predicate device. The device is used in conjunction with commercially available Zeiss-type Slit lamps.

The Z-type D-KAT uses the same Applanation Prisms as the predicate tonometer.

Method of Operation

In applanation tonometry the intraocular pressure is calculated from the force required to flatten a constant area of the cornea. Goldmann tonometry is considered to be the gold standard test and is the most widely accepted method in current practice.

The Z-type Digital Keeler Applanation Tonometer functions in accordance with the 'Goldmann method' i.e. the measuring of pressure to maintain a uniform applanation of the surface of the eye.

The Z-type D-KAT is used in conjunction with commercially available Zeiss-type Slit Lamps.

A disinfected or sterile disposable applanation prism is mounted on the Tonometer head at the end of the measurement arm and then placed against the cornea. The examiner then uses a cobalt blue filter to view two green semi circles, known as mires. The force applied to the Tonometer head is then adjusted using the rotating measurement drum connected to a variable tension spring until the inner edges of the green mires in the viewfinder meet. When an area of 3.06mm has been flattened, the opposing forces of corneal rigidity and the tear film are roughly approximate and cancel each other out allowing the pressure in the eye to be determined from the force applied.

Calibration Procedure

During factory setup / calibration procedure known pressures covering the measurement range are applied to the measurement arm using a calibration arm verified using the calibration procedure outlined in the Tonometer standard ISO 8612:2009.
Calibration procedure provides a relationship between the pressure applied to the measurement arm and the position of the rotating measuring drum. Linear interpolation is used between the calibration points.

Software

The software uses information stored / programmed during the factory setup / calibration procedure to monitor the position of the measurement arm against the position of the rotating measuring drum to determine the patients IOP which is displayed to the user on the LED display.

5. Labelling and Intended Use

Instructions for use (IFU) for the applanation tonometer have been updated to incorporate the change in shape of the device.

The intended use of the Z-type Digital Keeler Applanation Tonometer (D-KAT) as well as the method used by the clinician to obtain a reading remains unchanged by this modification.

"The Digital Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma."

6. Materials Biocompatibility

With respect to material that comes into direct contact intentionally with the eye, there are no changes.

7. Cleaning and Disinfection

Cleaning instructions for the tonometer body and the recommended method for disinfecting applanation prisms remains unchanged. Instructions have been provided in the Instructions for use.

8. Comparison of the device with the Predicate

The comparison table below summarizes the similarities and differences between both systems, with respect to safety and effectiveness, which are discussed in more detail in the following sections.

Characteristic Features	**Predicate Device – Digital Keeler Applanation Tonometer (T-type and R-type D-KAT)**	**Modified Device – Z-type Digital Keeler applanation Tonometer (Z type D-KAT)**	**Notes**
Type	Manual contact Tonometer	Manual contact Tonometer	No change
Indicated Use	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	No change
Intended Use	Intraocular Pressure (IOP) measurement	Intraocular Pressure (IOP) measurement	No change
Target Population	Patients with high IOP	Patients with high IOP	No change
Anatomical Sites	Cornea	Cornea	No change
Where Used	In a professional healthcare facility environment	In a professional healthcare facility environment	No change
Units of measure	mmHg - millimetre of mercury	mmHg - millimetre of mercury	No change
Design	Mounted on top illuminating (Haag-Streit-style) Slit lamp, manual dial	Mounted on bottom-illuminating (Zeiss-style) Slit lamp, manual dial	Change in shape of the device to allow mounting on bottom-illuminating slit lamp(Zeiss-type illumination

			system). The change does not affect the intended use, safety and effectiveness or the fundamental scientific technology.
Display	Numerical display - Direct reading of IOP in mmHg from display	Numerical display - Direct reading of IOP in mmHg from display	No change
Measurement Range	5-65mmHg	5-65mmHg	No change
Measurement technique	Applanation	Applanation	No change
Measurement Method	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	No change
Measurement deviation	0.49 mN or 1.5% of measurement value, whichever is the greater	0.49 mN or 1.5% of measurement value, whichever is the greater	No change
Power requirements	AA Battery to power digital display	AA Battery to power digital display	No change
Software	Contains software	Contains software	No change
Mounting method on slit lamp	Fixed (R-Type) and Take-away (T-Type)	Fixed	No change
Maintenance and Calibration	Maintenance and calibration required Factory set Calibration arm assembly is supplied with each device to check	Maintenance and calibration required Factory set Calibration arm assembly is supplied with each device to check	No change

	calibration	calibration	
Materials	Tonometer body - anodized aluminium; Tonometer prism – Medical grade acrylic	Tonometer body - anodized aluminium; Tonometer prism – Medical grade acrylic	No change
Biocompatibility	All materials are tested for biocompatibility	All materials are tested for biocompatibility	No change
Characteristic Features	Predicate Device - Keeler Applanation Tonometer (KAT)	Modified Device – Digital Keeler applanation Tonometer (D-KAT)	Notes
Type	Manual contact Tonometer	Manual contact Tonometer	No change
Intended Use	Intraocular Pressure (IOP) measurement	Intraocular Pressure (IOP) measurement	No change
Units of measure	mmHg - millimetre of mercury	mmHg - millimetre of mercury	No change
Design	Mounted on top-illuminating (Haag-Streit-style) Slit lamp, manual dial	Mounted on bottom-illuminating (Zeiss-style) Slit lamp, manual dial	Change in shape of the device to mount on Zeiss-type illumination system. The change does not affect the intended use, safety and effectiveness or the fundamental scientific technology.
Measurement Range	5-65mmHg	5-65mmHg	No change
Measurement technique	Applanation	Applanation	No change
Measurement Method	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	No change
Maintenance	Maintenance and	Maintenance and	No change

and Calibration	calibration required Factory set Calibration arm assembly is supplied with each device to check calibration	calibration required Factory set Calibration arm assembly is supplied with each device to check calibration	
Indicated use	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	No change
Mounting method on slit lamp	Fixed (R-Type) and Take-away (T-Type)	Fixed	No change
Measurement deviation	0.49 mN or 1.5% of measurement value, whichever is the greater	0.49 mN or 1.5% of measurement value, whichever is the greater	No change
Power requirements	AA Battery to power digital display	AA Battery to power digital display	No change
Software	Contains software	Contains software	No change
Display	Numerical display - Direct reading of IOP in mmHg from display	Numerical display - Direct reading of IOP in mmHg from display	No change

9. Performance and Safety

Verification tests have been carried out in accordance to the FDA guidelines “Tonometers – Premarket Notification [510(k)] Submissions” to confirm that the performance and safety aspects of the modified applanation tonometer are comparable with the Digital Keeler Applanation Tonometer cleared for marketing under 510(k) K133234.

The software used in the modified Z-type D-KAT has been verified against the requirements ISO 62304 Medical device software - Software life cycle processes.
The modified Z-type D-KAT has also been evaluated against the requirements of BS EN 60601-1 for electrical safety and to BS EN 60601-1-2 for electromagnetic compatibility.
In all tests the modified device was in compliance with these FDA recognized standards.

10. Substantial Equivalence

The modified Z-type Digital Keeler Applanation Tonometer is considered to be substantially equivalent to the Digital Keeler Applanation Tonometer described in the original 510(k) submissions (K133234).